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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,128	03/11/2002	Dennis M. Martin	550.0122USQ1	1510

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,128

Applicant(s)

MARTIN ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 12 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 12 and 15 are objected to because of the following informalities: in claim 12 the phrase "a stick" is repeated twice. In claim 15 the phrase "a barrier function enhancing agent" is repeated twice. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al. (U.S. Patent 5,364,617).

Bush et al. provides compositions and method for protecting the skin from the harmful effects of ultraviolet radiation, said effects comprising the premature aging of the skin, characterized, among others, by wrinkling and yellowing of the skin, cracking and loss of elasticity (See col. 1, lines 10-43).

With respect to the limitations of claims 1-3, that the claimed method of the invention is directed to the epithelia, and specifically to the lips, and the composition is applied to the epithelia for an effective period of time, the patent teaches that the topical compositions of the invention may be

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formulated in the form of lipsticks (See col. 18, lines 27-29) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Furthermore, the patent discloses a method and compositions for preventing the deleterious effects caused by UV exposure comprising applying to the skin compositions comprising a retinoid prior to, during or after UV exposure (See col. 25, lines 11-18 and col. 26, lines 5-21) Thus, the patent discloses a method comprising application of the topical composition of the invention to the epithelia, i.e. the lips, for an effective period of time, as claimed by Applicant.

With respect to the method of improving the aesthetic appearance of epithelia claimed in claim 1, and with regard to the limitations of claim 4, that the improvement in the aesthetic appearance is a reduction in the appearance of aging of the lips, and the limitations of claim 5, that said aging of the lips is photoaging or intrinsic aging, Bush et al. teaches that ultraviolet radiation causes premature aging of the skin (See col. 1, lines 36-38), discloses the use of a topical composition to prevent photoaging effects of exposure to the sun (See col. 4, lines 22-25) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Thus, the patent contemplates a method of improving the aesthetic appearance of epithelia and reducing the appearance of aging in the lips caused by UV exposure, i.e., photoaging, as claimed in claims 1, 4 and 5 of the instant application.

With regard to the improvement results claimed in claim 6 of the instant application, Bush et al. teaches that the premature aging caused by ultraviolet radiation is characterized, among others,

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by wrinkling and yellowing of the skin, cracking and loss of elasticity (See col. 1, lines 37-43).

The patent discloses a method and compositions for preventing the deleterious effects caused by UV exposure comprising applying to the skin compositions comprising a retinoid prior to, during or after UV exposure (See col. 25, lines 11-18 and col. 26, lines 5-21) and provides a method comprising topical application of a stick to the lips to inhibit damage caused by acute or chronic UV exposure (See Example IV). Since the method disclosed in the patent prevents premature photoaging, including wrinkling and yellowing of the skin, cracking and loss of elasticity, and is effective on lips, it inherently improves lip color and clarity by inhibiting yellowing, decreases lip dryness by preventing loss of elasticity and reduces vertical lip lines by decreasing wrinkling and cracking, as claimed by Applicant in claim 6.

Regarding the retinoid claimed in the method of claim 1 and the composition of claim 18, Bush et al. teaches that the photoprotection compositions of the invention preferably include a retinoid, which increases the wrinkle regulating benefits of the compositions (See col. 24, lines 63-68).

With respect to the penetration enhancing agent claimed in the method of claim 1 and the composition of claim 18, Bush et al. teaches that the topical compositions of the invention comprise an effective amount of 1-5% of the composition of a penetration enhancing agent (See col. 18, lines 43-55).

With regard to the amount of retinoid claimed in claim 7 of the instant application, Bush et al. teaches that a safe and effective amount of a retinoid in the compositions of the invention is

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0.001-2% of the composition (See col. 24, line 68 to col. 25, line 4). Thus, the patent discloses an amount range of retinoid as claimed by Applicant.

With respect to the limitation of claim 8, that the retinoid is retinol, Bush et al. includes Vitamin A among the retinoids used in the invention (See col. 25, lines 4-10). Retinol and Vitamin A are synonymous.

Regarding the penetration enhancing agents claimed in claims 9 and 10 of the instant application, Bush et al. includes organic solvents, and specifically propylene glycol and ethanol in the compositions of the invention (See col. 16, lines 23-45).

With respect to the cosmetically acceptable vehicle claimed in claims 11 and 12 of the instant application, Bush et al. teaches that the compositions of the invention may be made into a variety of products, including gels, sticks, sprays, pastes and cosmetics, which comprise solutions or emulsions (See col. 16, lines 15-22 and lines 46-63, and col. 17, line 2 to col. 18, line 29).

With regard to the limitation of claim 13, that the composition has a pH less than about 7.5, Bush et al. provides a method for the preparation of an emulsion useful for topical application to inhibit damage caused by acute or chronic UV exposure, and teaches that the pH of the emulsion is brought to 6.5 (See Example IX, col. 32, lines 7-20). Thus, the patent provides compositions having a pH less than 7.5, as claimed by Applicant.

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Regarding the anhydrous vehicle claimed in claim 14 of the instant application, Bush et al. provides solutions comprising organic solvents (See col. 16, lines 23-40) and discloses an ointment as carrier system, comprising animal or vegetable oils or oleaginous hydrocarbons (See col. 17, lines 18-21). The ointments comprising oils and the solutions containing organic solvents disclosed by the prior art are anhydrous vehicles, as claimed by Applicant in claim 14 of the application.

With respect to the secondary component claimed in claim 15, and specifically the sunscreen agents claimed in claims 16, 17 and 19 of the present application, Bush et al. teaches that preferred photoprotection compositions comprise a sunscreen agent and a retinoid (See col. 25, lines 11-18) and includes titanium dioxide among the sunblocks used in the invention and 2-ethylhexyl p-methoxycinnamate and butylmethoxydibenzoylmethane among the preferred sunscreens used in the compositions and method of the invention (See col. 20, line 35 to col. 21, line 38). The 2-ethylhexyl p-methoxycinnamate disclosed by the prior art corresponds to the octylmethoxycinnamate claimed by Applicant (the two terms are synonymous), and the butylmethoxydibenzoylmethane disclosed by the prior art is the chemical term for the compound avobenzene claimed by Applicant. Thus the patent provides the use of secondary components, and specifically sunscreens, as claimed by Applicant in claims 15-17 and 19 of the instant application.

The method and compositions disclosed by Bush et al. meet the limitations of claims 1-19 of the instant application, as the patent contemplates compositions comprising a retinoid and a

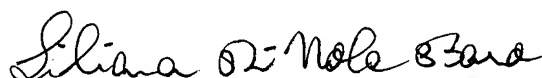
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penetration agent, and further comprising a sunscreen agent., and a method comprising applying said compositions to the lips. Thus, the patent anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.



August 13, 2003

Liliana Di Nola-Baron

Patent Examiner

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